UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,883	06/22/2006	Stefan Golz	2004P56027 WOUS	5304

28524 7590 11/03/2010

SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
170 WOOD AVENUE SOUTH
ISELIN, NJ 08830

EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
11/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,883	GOLZ ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-17 and 19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group IV (claim 18) and species of gastroenterological disease in the reply filed on 10/06/2010 is acknowledged.
2. Applicants' preliminary amendment filed on 03/20/2006 has been entered in full. Claims 1-26 are pending. Claim 18 is under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention

Information Disclosure Statement

3. The information disclosure statements filed on 03/20/2006 has been considered by the examiner.

Drawings

4. The drawings filed on 03/20/2006 are accepted by the Examiner.

Claim Rejections—35 USC § 112, 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 18 is drawn to a method of diagnosing a gastroenterological disease in a mammal comprising determining the amount of AdipoR1 polynucleotide in a sample from a mammal. The claim is broad because gastroenterological diseases encompass a broad range of diseases affecting gastrointestinal tract (See page 60 of the specification) in any mammals. Moreover, the claim does not provide a structural limitation for the AdipoR1 polynucleotide to be detected.

The sequence search reveals that the AdipoR1 polynucleotide of SEQ ID NO: 1 is known in the prior art (see, e.g., Friedman et al., WO200298898-A2, December 12, 2002). However, there are no teachings in the art that an artisan could potentially diagnose a gastroenterological disease in a mammal by detecting a AdipoR1

polynucleotide of SEQ ID NO: 1 or a variant thereof.

The instant disclosure does not provide sufficient guidance/direction or working examples on how to diagnose a gastroenterological disease in a mammal. The instant specification asserts that the human AdipoR1 is highly expressed in the tissues of gastroenterological system: stomach, stomach tumor, small intestine, rectum, and the rectum tumor (page 61, last paragraph). Table 1 (page 103) lists the results of the mRNA-quantification (expression profiling) in various tissues. However, there is no sufficient information or experimental data presented on whether the expression level of the human AdipoR1 polynucleotide of the present invention can serve as a reliable diagnostic marker for a gastroenterological disease in a human subject, needlessly to say in a mammal. For example, the expression levels of AdipoR1 polynucleotide in colon and colon tumor are nearly the same (Table 1, page 103). The expression levels of AdipoR1 polynucleotide in rectum and rectum tumor are also in the same numerical order, 1563 versus 3397 (Table 1, page 103). While there are about 20-fold difference in the expression levels of human AdipoR1 polynucleotide in stomach and stomach tumor, it is unclear how many samples were performed. The specification does not provide any statistical data.

The skill in the area of diagnosing a disease by determining the expression level of a polynucleotide is generally high. However, without knowing a correlation between a particular gastroenterological disease and the expression level of a specific AdipoR1 polynucleotide, it is unpredictable whether a gastroenterological disease in a mammal can be diagnosed by determining the amount of AdipoR1. It

would take undue experimentation for one skilled in the art to make and use the claimed invention without sufficient guidance, working examples, and knowledge about correlation between a particular gastroenterological disease and the expression level of a specific AdipoR1 polynucleotide.

Accordingly, specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the AdipoR1 polynucleotide of present invention as a diagnostic marker for diagnosing a gastroenterological disease in a mammal

7. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claim 18 is drawn to a method of diagnosing gastroenterological disease in a mammal comprising determining the amount of AdipoR1 polynucleotide in a sample from a mammal. The claim does not require that the AdipoR1 polynucleotide possesses any particular conserved structure nor other disclosed distinguishing

feature. Thus, the claim encompasses a genus of AdipoR1 polynucleotide without any structural features.

The instant disclosure of AdipoR1 nucleic acid molecule of SEQ ID NO: 1 that encodes the AdipoR1 polypeptide of SEQ ID NO: 2 does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case, one species is not sufficient to support the broad genus of AdipoR1 polynucleotides. Furthermore, while teaching a polynucleotide comprising the nucleic acid sequence of SEQ ID NO: 1 (see, e.g., Friedman et al., WO200298898-A2, December 12, 2002), the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed polynucleotides.

Due to the breadth of the recited genus and lack of the definitive structural features of the recited genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the recited genus.

Claim Rejections—35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite because the steps of the method do not necessarily achieve the goal set forth in the claim preamble. It is unclear how the disease is diagnosed or how the amount of AdipoR1 polynucleotide is linked to the disease.

Claim 18 is indefinite because it recites the acronym, "AdipoR1". First, such a term is determined arbitrarily without a definitive structure. Others in the field may isolate the same polynucleotide and give an entirely different name. Thus, reciting biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly point out what the polynucleotide is. Applicants should particularly point out the AdipoR1 polynucleotide by reciting characteristics associated with the polynucleotide, such as a sequence identifier (SEQ ID NO).

Claim Objection—Minor Informalities

10. Claim 18 is objected to because of: (i) it recites non-elected subject matter; (ii). it recites in step ii) "and/or ". Appropriate correction is required.

Conclusion

11. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

November 2, 2010